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The Effect and the determinants of Behavioral and Motivational therapy among Children with Enuresis in Kindergarten, Makkah Al-Mukarramah,Saudi Arabia, 2018 A randomized control trial.

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Abstract

Background: There are different strategies in the management of enuresis can be usedby parents using one or combinationof interventions including behavioral, motivational intervention, enuresisalarm and medications.

Objective: To measure the effect of behavioral and motivational therapy in improving the enuresis and factors associated with that among the intervention group compared with the control group in kindergarten in Makkah Al-Mukarramah, 2018.

Methodology: Randomized control trial was carried out among children (3-6 years) attending kindergarten. The control group includes enuretic children treated with behavioral therapy while the intervention group treated with behavioral therapy and motivational therapy (star chart). The child was considered improved if he/she has zero wetting per week for 2 consecutive weeks.

Results: Eighty-two enuretic children were included in the study. The response rates were 73.8% and 85% at 3rd month among both intervention and control groups, respectively $p>0.05$. The improvement in enuresis was 16.5% among the participants in first month, whereas it increased to 35.6% in the second month, then slightly declined inthe third month 35.4%.There was no statistically significant difference between both groups regarding the improvement in enuresis. Concerning the factors associated with improvement in enuresis, only two factors were identified; the economic status of the child's family $p<0.05$ and frequency of nocturnal enuresis at baseline $p<0.04$.

Conclusion: This study revealed that motivational therapy did not add to the improvement produced by behavioral therapy.

Keywords: *behavioral therapy, Enuresis, Improvement, kindergarten, motivational therapy.*

I. Introduction

1.1Background

Enuresis is a frequent involuntary loss of urine on the bed during sleep or clothes during waking at least two times per week for three consecutive months in the absence of congenital or acquired defects of the urinary tract or central nervous system. [1][2][3]

This condition generallyconsiders benign while it causes

a significant impact on children and their families such as low self-esteem, social irritation, and sleep disturbance.[1][4]

Enuresis can be classified into monosymptomatic nocturnal enuresis (MNE)and non-monosymptomatic nocturnal enuresis (NMNE). MNE when the patient has enuresis without any urinary symptom and Constitute approximately 85% of cases, where as NMNE when the patient has enuresis with urinary tract symptoms such as urgency, frequency, weak stream, dribbling, and incomplete emptying.[3][5]

The MNE may subdivideinto primary and secondary enuresis.The primary enuresis refers to children who had never been dry for a prolong period while secondary enuresis refers to children who dry for a period of time then become enuretic later.[4][5]

There are different strategies in the management of enuresis can be used by parents to help their child to stay dry and may involve one or combination of interventions such as behavioral intervention, motivational therapy, enuresis alarm, and medication.[1]

The simple behavioral intervention, education, lifestyle modification, and motivational therapy consider the best first-line treatment to be used in children less than seven years.[1][6]

There is a differentsimple behavioral intervention that helpsthe child to stay dry such as wakening or lifting the child tothetoilet, fluid restriction, bladder training, and are ward chart.[7]

1.2 Rationale

Because the enuresis is one of the common problems in the pediatric age group and prevalence is high according to previous studies [3]

From the researcher's point of view, this problem affects the most important individuals in the family (the child and the mother) hence the whole family will be affected.

Furthermore, there is lack of knowledge in the society about behavioral and motivational therapy. In addition, this line of treatment considers goodfirst-line in younger children less than seven years. It is better to start the treatment earlier in this age group to avoid the psychosocial impact onchildren.

Moreover, the parents have an important role in the treatment through encouraging and supporting their child. The researcher aims at increasing the level of awareness and ability of parents to deal properly with their enuretic children.

1.3Aims

To assess the effect of the motivational therapy among children withenuresis, with decreasing the prevalence of the problem and increase the ability of mothers to deal properly with enuretic children.

1.4 Objectives

- To measure the effect of behavioral and motivational therapy in improving the condition of children with enuresis among intervention group compared with control group in kindergarten in Makkah Al-Mukarramah, 2018.
- To determine factors associated with enuresis improvement rate among intervention group compared to a control group in kindergarten at Makkah Al-Mukarramah, 2018.

II. Literature review

Definition

According to the diagnostic and statistical manual of mental disorder 5th edition (DSM-5) the enuresis is defined as intentional or involuntary frequent voiding of urine into clothes or bed at least two times per week for three consecutive weeks in children 5 years of age or older causing significant stress and impairments of functioning with absences of secondary cause such as diabetes mellitus, medication , seizure disorder and spina bifida.[8]

Prevalence and associated factors

Alshahrani et al. conducted a cross-sectional study in 2017 to estimate the prevalence of NE among children in a primary health care center in Riyadh and to identify the characteristic of children who has NE. The study showed that 18.5% of families have children with NE. The frequency of bed witting nightly is 38.7% and 56.5% every week and 11.3% of children had diurnal enuresis as well. They found many children having stressful events like parental divorce (6.5%) and birth of a new baby (22.6%). About 93.5% of children had no disease and 6.5% had diabetes. Furthermore, 58.1% of children don't have a family history of NE and 62.9% of those children were circumcised. Out of 65 families that had children with NE, nineteen families (29%) tried to treat the enuresis of their children. Four (6%) families justified their answer not to treat their children because they found their children improving over time. Eight (12%) families who attempted to treat their children used fluid restriction and often woke up their children to urinate at night. Four (6.1%) families who attempted to treat their children used fluid restriction in addition to medical consultation as their mode of treatment. Nineteen (29%) families reported that their children responded to treatment. Also, 19 (29%) families agreed that their children needed further health advice.[9]

In 2014, a study carried out by Tuncay tas et al. to determine the relationship between MNE and seasonal temperature changes during the cold season (from December to March) and the hot season (from June to September). The researchers conducted the study on 75 children with MNE selected from pediatric and urology clinic. They assess the rate of enuresis during summer and winter months in nightly, weekly and monthly intervals by questionnaire. The study concluded that there is a difference in the ratio of enuresis in 48 out of 75 enuretic patients between winter and summer months. The nightly, weekly, and monthly ratios are higher in children with MNE in winter months.[10]

In 2013, a cross-sectional study conducted in Makkah Al-Mukarramah by Najjarto determine the prevalence and factors associated with enuresis among primary school children. The study concluded that the prevalenceof NE among primary school children was 8.6 %. The enuresis was more frequent among children at the age of 8 years, those who live with either mother or father, with history of parental consanguinity, families with low-income, fathers with low education level, living in smaller number of rooms, those having stool incontinence ,recurrent UTI, habit of eating fast foods or chocolate at dinner, psychological issues (changing home or school, separation of parents, loosing of lovable personand acute family problem) and those having family history of enuresis.[11]

Methods of Management

Kuwertz-Bröking E et al. 2017, published a study about the clinical management of NE. The study revealed that the choice of treatment depends on the type of enuresis (MNE, NMNE), presence of other illnesses,the severity of the disease, the child's interest in treatment and abilities of caregivers to care for their children. If there is a history of constipation combined with enuresis should be treated first by use of a laxative. If there is a history of diurnal enuresis or urinary symptoms in (NMNE) should be addressed and treated. The first-line treatment for all types of enuresis is behavioral therapy which includes decreasing the fluid intake in theevening, using of calendar for the wet and dry night , about 15-20% of enuretic children stay dray with this method. If no improvement by behavioral therapy alone another modality of treatment can be tried such as desmopressin or enuresis alarm. Enuresis alarm is the most effective long-term therapy and requires long term adherence for at least three to four months. If no response after six weeks either stop using the alarm or use other modalities with

the alarm (desmopressin, behavioral therapy). The response rate to enuresis alarm after ten to twelve weeks of treatment noted between 50 to 80%. The relapse rate is about 12 to 30 % withinsix months of treatment. Desmopressin is one of the pharmacological treatments for enuresis which decreases the urine production at night. The response rate to treatment noted between 60 to 70% with a high relapse rate. Imipramine tricyclic antidepressant is another pharmacological treatment used for an enuretic child with a response rate of 40 % and a higher relapse rate after stopping the medication.(12)

In 2016, Pediatric child health published a study about the management of primary nocturnal enuresis. They concluded that behavioral therapy such as wakening child to bathroom and star chart may consider a successful option for some children. The mockery, humiliation, and punishment should be avoided.(6)
In 2016, Glazener et al. carried out a systematic review of 13 trials including 387 children out of 702 received behavioral therapy aimed to evaluate the effects of simple behavioral interventions on children with NE versus other interventions. They concluded that star charts, waking the child to void in toilet effective in the management of enuretic children compared to control groups.(13)

In 2015, Perrin N et al. conducted a systematic review of 8 randomized controlled trials to assess the efficacy of enuresis alarm versus desmopressin in the treatment of primary monosymptomatic NE.Studies involving children aged between 5 and 17 years with primary monosymptomatic NE treated with either desmopressin or enuresis alarm. Seven studies showed no statistical difference when treatment stopped between enuresis alarm and desmopressin group regarding nocturnal continence improvement. Four studies revealed higher relapse rate with desmopressin withdrew compared to enuresis alarm. The overall conclusion from 8 studies noted that the enuresis alarm was more effective for long term in the management of NE than desmopressin.(14)
In 2014, the International Journal of Medical Science and Public Health had published an article conducted by ALmatrafi H targeted to finding and evaluating the scope of improvement and factor associated with it among children attending the enuresis clinic at Rusaifah Family Medicine Postgraduate Training Center in MakkahAl-Mukarrmah. The researcher conducted the study on 150 patients with enuresis registered with enuresis clinic at Rusaifah Family Medicine Postgraduate Training Center.The modality of treatment used for patients in the clinic was behavioral intervention such as fluid restriction, voiding before going to bed and alleviation of stressor moreover motivational intervention by star chart.The response rate to treatment was near to 100% among 149 patients (99.3%) in the first month, (36%) and (6%) in the 2nd and 3rd month respectively.(15)
A systematic review carried out in 2013 by Caldwellet al. to determine the effects of simple behavioral interventions in children with enuresis.Tested a total of sixteen trials shown that thesimple behavioral intervention is better than no treatment for enuretic patient .(7)
The journal of pediatric published a randomized control trial in 2009 to assess the short- and long-term effects of three simple behavioral interventions to overcome nocturnal enuresis inyoung children in Leiden in SouthHolland.Theresearcherdivided the 570 enuretic children into four groups through a computer database (access) each groupcontains 134 children.Thefourgroups were: first group Waking and lifting the childtothebathroom and ask for a password, second groupWaking and lifting the child to the bathroom without asking for a password, third group using of reward and star chart, fourth group control groupwith written and printed instruction given for each group.They concluded that walking and lifting children tothebathroom is more effective inthedryness of enuretic children than no treatment after six months.Furthermore, the use of a reward system (star chart) isthemore effective treatment of NE in the first 15 weeks while walking and lifting the child to the bathroom withoutapassword is more effective after 15 weeks.(16)

III. Methodolgy

3.1Study Design

A randomized control trial,interventionalstudy. Figure1: Flow chart of the study

3.2Study area

The kingdom of Saudi Arabia located in the Arabian Peninsulain the far south-west of Asia. It occupies four-fifths of the Arabian Peninsula with an area of about 2,000,000 square kilometers.(17)

Makkah Al-Mukarramahis the holy capital ofSaudi Arabia; itis locatedin thewesternregion; it provides a lot of services such as medical and educational services throughgovernmental and private institutes.

Makkah region includes eightsectors; five of them inside the city and the total number of kindergarten are 148 according to the Statistical guidebook of the Ministry of Education for Kindergarten Schools.[18]

3.3 Study location

Private and governmental Kindergartens which are located in Makkah Al-Mukarramah.

3.4Study groups

Group 1: Enuretic childrenin kindergartens who have been treated only by behavioral therapy.
Group 2: Enuretic children in kindergartens who have beentreated by behavioral therapy and motivational therapy by star chart.

Eligibility criteria

3.5Inclusion criteria

- Children in kindergarten with Enuresis at least two times per weekin last three consecutive months.
- Boys and girls aging fromthree to six years.
-All nationalities.

3.6 Exclusion criteria

- All Children in kindergarten with no history of enuresis.
- All Childrenwith organic disease.
- All Children with enuresis in kindergarten outside Makkah city.

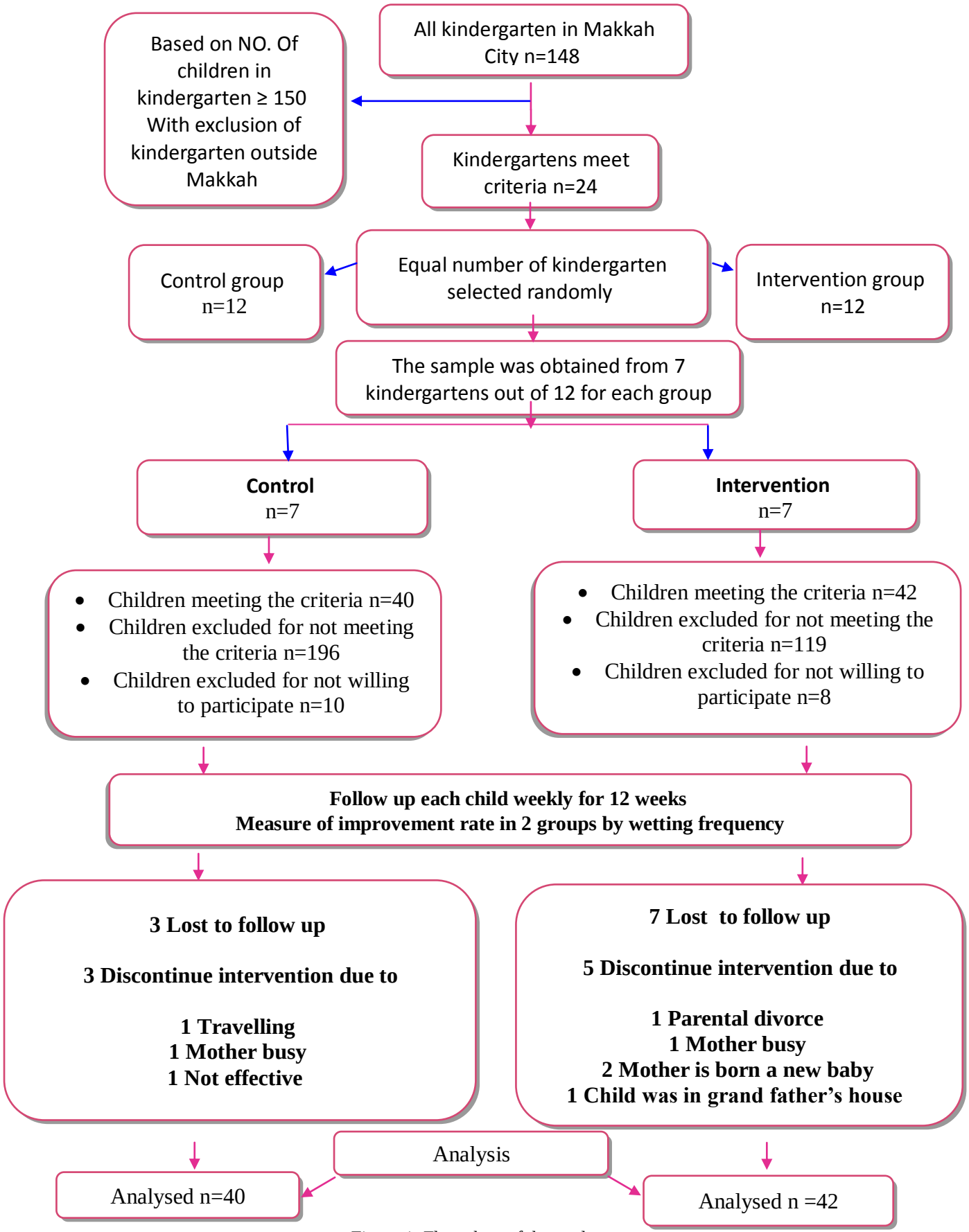

Figure 1: Flow chart of the study

3.7 Sample size

By using an online sample size calculator from www.epitools.com.The sample size at least 40 children in each group to detect a difference of 32% in improvement rate of nocturnal enuresis pre and post behavioral therapy along with motivational therapy. (assuming a 32% success rate in the intervention group according to the previous study[16]). Accepting a confidence level of 95% and power of 80%. Figure 2: sample size

The null hypothesis is set to be: there is no statistically significant relationship between improvement of enuresis among children with enuresis who received motivational therapy along with behavioral therapy and enuretic children who just received behavioral therapy.

The alternative hypothesis is set to be: there is a statistically significant relationship between improvement of enuresis among children with enuresis who received motivational therapy along with behavioral therapy and enuretic children who just received behavioral therapy.

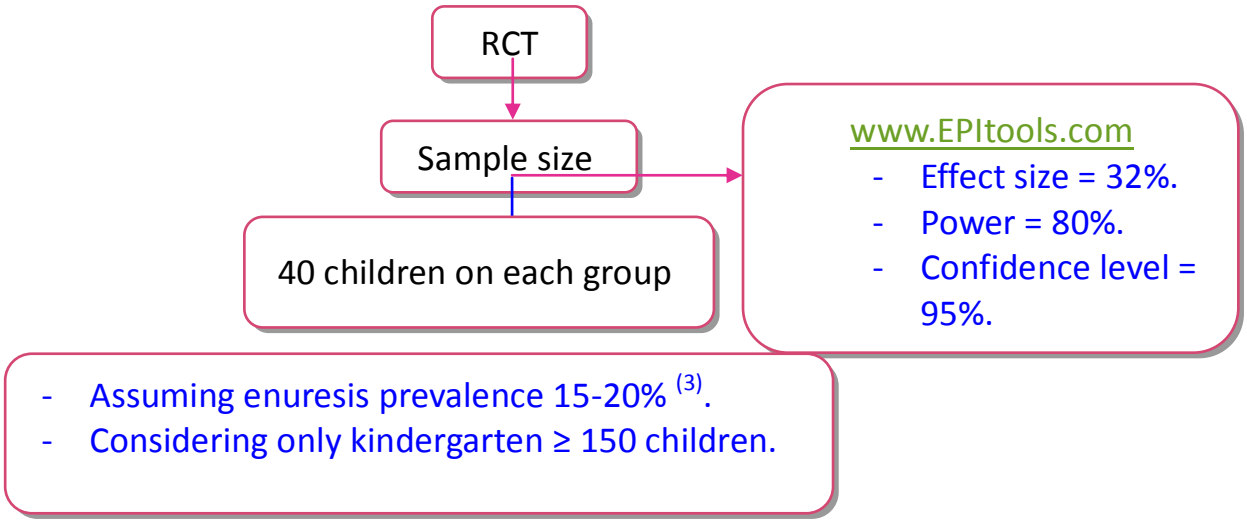

Figure 2: sample size

3.8 Sampling technique

Assuming enuresis prevalence 15-20% according to previous study[3]The sample size was obtained from 24 kindergartens out of 148 in Makkah Al-Mukarramah chosen based on the number of children in institute equal or more than 150 with exclusion of kindergartens outside Makkah City, each kindergarten coded by number started from the number (1,2,3and so on).Randomly twelve kindergartens were considered as an intervention group and the remaining twelve in a control group by using of random number integers by the researcher. A sample of 40 enuretic children was obtained from seven out of twelve randomly chosen kindergartens for each group by using a random number generator by the researcher.These kindergartens named:2nd,3rd,5th,12th,19th, Ola Makkah, Ebdaa Altofola, Children'sgarden, Bshaer Alebdaa, Geil Aliman, Nwabegh Alebdaa,Toyor Almajd, ALabnaa Alnojbaa and AL-Bushra private kindergarten. All children in kindergartens with enuresis and they meet the criteria included in the study regardless of the required sample size as calculated; this measure was carried out due o ethical reason.

3.9 Data collection tool

- Electronic questionnaire to determine whether or not a child has enuresis was used.
- Self-administrating questionnaire to be filledbyparents of enuretic children to assessfactors associated with improvement of enuresis.

The questionnaire designed in the Arabic language with cover letter to clarify the objectives of the study and assurance of confidentiality along with the consent paper signing to allow their children to participate.

It is consist of 4 sections:

First section: personal data.

Second section: information for enuresis.

Third section : possible factor associated with enuresis improvement.

Last section: parental attitude.

- Educational video in the Arabic language made by the researcher one for intervention group and the second for the control group.
- A printed copy of instructions about behavioral therapy for both groups along with printed enuresis diary for the control group and star chart for the intervention group.

3.9.1 Validity of questionnaires

The researcher used a validated questionnaire from the previous study[11] and some modifications were done, after that, it wasvalidated by two consultants.

3.10 Data Collection Technique

The study was initiated after obtaining approval from Saudi board of Family Medicine Research Committee and from Joint Program of Family Medicine and Ministry of Education in Makkah.After that, the researcher gave the official approval papers from the Ministry of Education to the director of each kindergarten. The researcher designed two electronic questionnaires one was sent to the directors of seven randomly chosen kindergartens in the intervention group and the second to the directors of seven randomly chosen kindergartens in the control group to send it to each mother by whatsapp mobile application to determine if their children have enuresis or not.After that, self-administrated questionnaires in an envelope coded by number to ensure confidentiality were distributed by the researcher toenuretic childrento be submittedto their parents. Parents were instructed to fill the questionnaire and return it to the kindergarten in an envelope with their children the next day. Questionnaires were collected on the second day.After that,the researcher contacted mothers of all children with enuresis individually inbothinterventionand control groupfor education and counseling. The mothers of both groupshave an option to choose one of the social communication methods to receive the treatment plan.

The treatment plan was a form of a video (white board animation) made by the researcher about basic enuresis information, types, causes, associated factors and how to deal with enuretic children through behavioral therapy for both groups.

This behavioral therapy is in form ofalleviation of the stressor (punishment and mockery), decrease the fluid intake before sleep,avoid diuretic food and drinks,avoid wearing child diapers and voiding before going to bed.

Further more, the motivational therapy that was carried outby star chart and rewards only for intervention group in the way of how to apply the motivational therapy by star charts. Each dry morning is rewarded by a star, and five stars in a week were rewarded by a gift chosen by the child or parents. Moreover, each group was given a copy of instructions about strategy of behavioral therapy through whatsapp mobile application. Further more, a copy of enuresis diary to completed by parents in a control group by applying checkmark following every dry night and X mark following wet night for 12 weeks and acopy of star chart for intervention group was given to parents and the parents instructed to apply or draw star by child or parents for each day following a dry night for 12 weeks and to provide rewards chosen by child or parents after five dry nights per week.At the end of each week, each mother received a reminder letter to send enuresis diary and star chart to the researcher to look for improvement in enuresis frequency per week. The researcher is the only one who aware of the allocation of each group, whereas the participants in the control group were blind from the provided intervention in an intervention group.To reduce the contamination and co-intervention each group was instructed not to apply any external interference other than given instructions and intervention and if there is any intervention used by parents, the researcher should be informed.

The child considers improved if he has zero wetting per week for 2 consecutive weeks.[16][19] The study would finish after 12 weeks even if the child still has enuresis.

3.11 Expected study outcome

The expected primary outcome was at least 32% improvement of enuresis pre and post-intervention[16].

3.12 Study variables

3.12a. Dependentvariables

The improvement rateof enuresis among children

3.12b. Independent variables

Age, Gender, Nationality, Age of toilet training,Types of enuresisWetting frequency, Past stressful events, Presence of Urinary tract infection symptoms, Constipation, Fecal soiling, Organic disease, Health problem, Habitual factors, Impact of enuresis,Parent's attitude, Enuresis in Parents, Parent's consanguinity Parental education, Type of housing, No. of room in home, No. of bedroom, No. of bathroom in home and Income.

3.13 Data entry and analysis

- Statistical program for social sciences(*SPSS*) with a version25was used.
- Description of variables was done using frequency and percentage for categorical variables.
- PearsonChi-square and Fisher exact tests were used for comparison of categorical variables between the two groups.
- Since the outcome variables (number of wetting nights/week) and diurnal wetting (days/week) were abnormally distributed (significant K-S test), non-parametric tests were used for analysis. Mann-Whitney test was used to compare between the two studied groups. Wilcoxon signed rank test was used to compare findings at baseline with those at follow-up periods.
- Significance: P-value < 0.05was consider for statistical significance.

3.14 Pilot study

A pilot study was conducted on 10 % of children in two kindergartens (out of the study area). As a feedback, the method of the study and study were clear and no modifications were requested.

3.15 Ethical considerations

- Approval from Saudi board of Family Medicine Research Committee and from Joint Program of Family Medicine in Makkah was obtained before conducting the research.
- The research protocol was approved from the Institutional Review Board of Security Forces Hospital Makkah.
- Written Permission from the ministry of education was obtained.
- Written consent was obtained from parents.
- Phone Permission withdr/alnajjar for taking and modification on his questionnaire.
- All information remains confidential and not be accessed except for the purpose of scientific research.
- Acknowledgments for all supervisors, advisors, helpers, facilitators, parents indicating their role in the research process.

3.16 Limitations

The time is limited.

There was a lack of cooperation from some kindergarten’s director and some mother’s of enuretic children.

There was a possibility of co intervention to help their child to achieve more star or checkmark and stay dry.

3.17 Budget

Self funded

IV. Result

4.1Response Rate

Figure 3 demonstrates the response rate in both intervention and control groups. In intervention group, it was 100% at baseline and became 73.8% at the third month of follow up while in control group,it was 100% and became 85% at third month of follow up with no statistical significance between both groups.

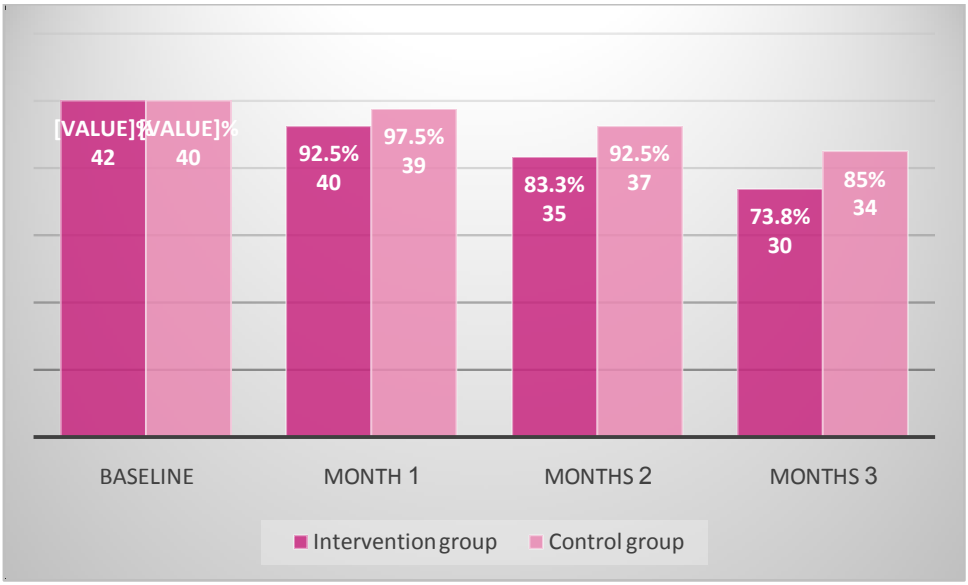

Figure 3: Response rate of the participants in intervention and control groups

4.2 Demographic characteristics

A total of Eighty two enuretic children were included in the study (42 in an intervention group and 40 in a control group)and 64 were followed up to the end of the study. The 18 patients who did not complete the study included 12 patients from an intervention group and 6 patients from a control group. Table 1 presents their demographic characteristics. More than half of them (56.1%) were males and 40.2% aged between over 5 and 5.5 years whereas 36.6% aged between over 5.5 and 6 years. The majority of them (95.1%) were Saudis. Regarding toilet training, it was at or below 2 years in 29.3% of children and at or above 3.5 years in 15.9% of them. The majority of the children (87.8%) live in flats. More than half of them (54.3%) had 4 or less rooms at their residence, 70.4% had two or less bedrooms and 42.7% had two or less bathrooms. More than half of their fathers (55.6%) and 68.3% of their mothers were university-educated or above. Parental consanguinity was observed among 23.2% of the enuretic children. Majority of the children (92.7%) live with both parents. The income (SR/month) ranged between 8001 and 10000 among 27.8% of the children whereas it exceeded 10000 among 24.1% of them. There were no significant differences between the intervention and control group in all demographic characteristics.

Table 1: Demographic characteristics of the participants

	Intervention group **n**=42 N (%)	Control group **n**=40 N (%)	Total 82 N (%)	p-value
Gender				
Male	20 (47.6)	26 (65.0)	46 (n=56.1)	non-
Female	22 (52.4)	14 (35.0)	36 (43.6)	significant(NS)*
Age (years)				
3-5	7 (16.7)	12 (30.0)	19 (23.2)	
>5-5.5	19 (45.2)	14 (35.0)	33 (40.2)	
>5.5-6	16 (38.1)	14 (35.0)	30 (36.6)	NS*
Nationality (n=81)				
Saudi	39 (92.9)	38 (97.4)	77 (95.1)	
Non-Saudi	3 (7.1)	1 (2.6)	4 (4.9)	NS**
Age at toilet training (years)				
≤2				
2.5	12 (28.6)	12 (30.0)	24 (29.3)	
3	11 (26.2)	12 (30.0)	23 (28.0)	
≥3.5	11 (26.2)	11 (27.5)	22 (26.8)	
	8 (19.0)	5 (12.5)	13 (15.9)	NS*
Type of housing				
Flat	37 (88.1)	35 (87.5)	72 (87.8)	
Others	5 (11.9)	5 (12.5)	10 (12.2)	NS*
Number of rooms (n=81)				
≤4	19 (46.3)	25 (62.5)	44 (54.3)	
>4	22 (53.7)	15 (37.5)	37 (45.7)	NS*
Number of bedrooms (n=81)				
≤2				
>2	27 (65.9)	30 (75.0)	57 (70.4)	
	14 (34.1)	10 (25.0)	24 (29.6)	NS*
Number of bathrooms				
≤2	15 (35.7)	20 (50.0)	35 (42.7)	
3	19 (45.2)	16 (40.0)	35 (42.7)	
≥4	8 (19.0)	4 (10.0)	12 (14.6)	NS*
Paternal education (n=81)				
≤Secondary //Diploma	15 (35.7)	21 (52.5)	36 (44.4)	
University/above	27 (64.3)	19 (47.5)	45 (55.6)	NS*
Maternal education				
≤Secondary/Diploma	11 (26.2)	15 (37.5)	26 (31.7)	
University/above	31 (73.8)	25 (62.5)	56 (68.3)	NS
Parental consanguinity				
Yes	10 (23.8)	9 (22.5)	19 (23.2)	
No	32 (76.2)	31 (77.5)	63 (76.8)	NS*
With whom child live				
Both parents	39 (92.9)	37 (95.5)	76 (92.7)	
Mother	3 (7.1)	3 (7.5)	6 (7.3)	NS**
Income (SR/month) (n=79)				
≤5000	9 (22.5)	12 (30.8)	21 (26.6)	
5001-8000	8 (20.0)	9 (23.1)	17 (21.5)	
8001-10000	12 (30.0)	10 (25.6)	22 (27.8)	
>10000	11 (27.5)	8 (20.5)	19 (24.1)	NS*

* Pearson chi-square ** Fischer exact test NS = non-significant

4.3 Risk factors:

It is shown in table 2 that 15.9% of the children with enuresis eat chocolate at or after dinner either always or often. Only 2.4% have taken beverages at or after dinner either always or often. Majority of them (90.2%) and 73.2% never drink coffee or tea, respectively at or after dinner. Regarding important life events in the early years of life, having new siblings and changing home/school were reported by 58.5% and 30.5% of the children, respectively. Hospital admission, surgery and family history of acute psychiatric or social problems were observed among 14.6%, 11% and 11% of the children, respectively.A family history of nocturnal enuresis was reported by 36.6% of the children as illustrated in figure 2.

The only significant factor between the compared groups was the history of surgery early in life as 19% of children in the intervention group compared to only 2.5% of those in the control group had such history, $p<0.02$.

Table 2: Distribution of the risk factors for enuresis among the participants

	Intervention group **n**=42 N (%)	Control group **n**=40 N (%)	Total 82 N (%)	p-value
Eating chocolate at or after dinner				
Always	3 (7.1)	2 (5.0)	5 (6.1)	
Often	5 (11.9)	3 (7.5)	8 (9.8)	
Sometimes	15 (35.7)	15 (37.5)	30 (36.6)	
Rarely	15 (35.7)	10 (25.0)	25 (30.5)	
Never	4 (9.5)	10 (25.0)	14 (17.1)	NS*
Intake beverages at or after dinner				
Always	0 (0.0)	1 (2.5)	1 (1.2)	
Often	1 (2.4)	0 (0.0)	1 (1.2)	
Sometimes	6 (14.3)	6 (15.0)	12 (14.6)	
Rarely	8 (19.5)	3 (7.5)	11 (13.4)	
Never	27 (64.3)	30 (75.0)	57 (69.5)	NS*
Drinking coffee at or after dinner				
Always	0 (0.0)	0 (0.0)	0 (0.0)	
Often	0 (0.0)	0 (0.0)	0 (0.0)	
Sometimes	3 (7.1)	1 (2.5)	4 (4.9)	
Rarely	1 (2.4)	3 (7.5)	4 (4.9)	
Never	38 (90.5)	36 (90.0)	74 (90.2)	NS*
Drinking tea at or after dinner				
Always	0 (0.0)			
Often	0 (0.0)	1 (2.5)	1 (1.2)	
Sometimes	6 (14.3)	0 (0.0)	0 (0.0)	
Rarely	8 (19.0)	4 (10.0)	10 (12.2)	
Never	28 (66.7)	3 (7.5)	11 (13.4)	
		32 (80.0)	60 (73.2)	NS*
Family history of nocturnal enuresis				
Yes	12 (28.6)	18 (45.0)	30 (36.6)	
No	30 (71.4)	22 (55.0)	52 (63.4)	NS*
Events in early years of life				
Having new siblings	23 (54.8)	25 (62.5)	48 (58.5)	NS*
Parental separation	3 (7.1)	1 (2.5)	4 (4.9)	NS**
Separation from mother for more than one month	2 (4.8)	0 (0.0)	2 (2.4)	NS**
Changing home/school	14 (33.3)	11 (27.5)	25 (30.5)	NS*
Hospital admission	6 (14.3)	6 (15.0)	12 (14.6)	NS*
Surgery		1 (2.5)	9 (11.0)	0.018**
Loss of admirable person	8 (19.0)	3 (7.5)	4 (4.9)	NS**
Family history of acute psychiatric or social problem	1 (2.4) 4 (9.5)	5 (12.5)	9 (11.0)	NS**

* Pearson chi-square** Fischer exact test NS = non-significant

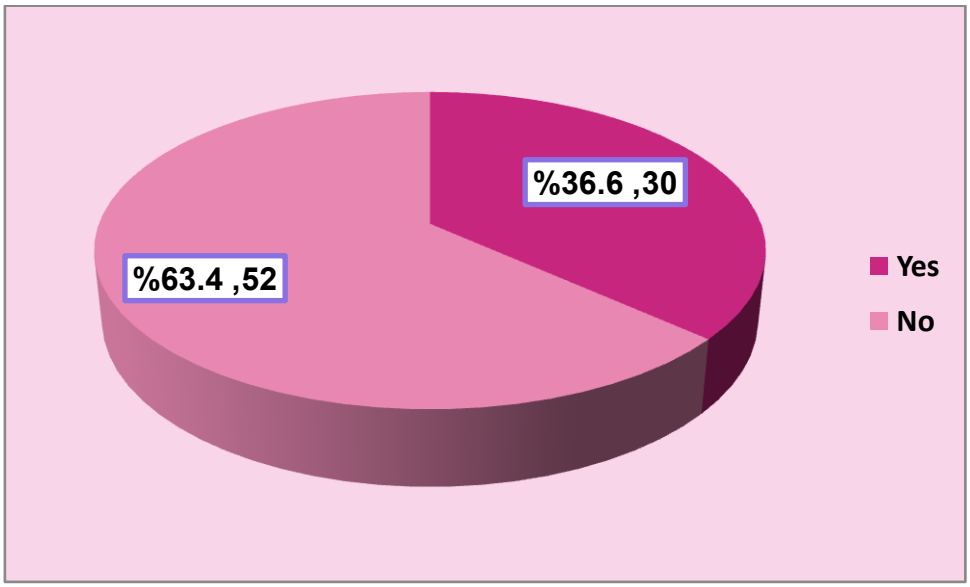

Figure 4: Family history of nocturnal enuresis among the children.

4.4 Associated symptoms :

Dysuria was either often or sometimes reported by 3.7% of the enuretic children while weak stream was reported sometimes by 6.2% of them. Divided stream and hematuria were sometimes reported by 4.9% and 1.2% of the participants, respectively. Frequency and urgency were reported always or often by 11% and 7.4% of the children, respectively. There was no statistically significant difference between the compared groups regarding symptoms associated with enuresis as illustrated in table 3.

Table 3: Distribution of the associated symptoms of enuresis among the participants

	Intervention group **n**=42 N (%)	Control group **n**=40 N (%)	Total 82 N (%)	p-value*
Dysuria**				
Often	1 (2.4)	0 (0.0)	1 (1.2)	
Sometimes	1 (2.4)	1 (2.5)	2 (2.5)	
Rarely	7 (17.1)	5 (12.5)	12 (14.8)	
Never	32 (78.0)	34 (85.0)	66 (81.5)	NS
Weak stream**				
Sometimes	3 (7.3)	2 (5.0)	5 (6.2)	
Rarely	3 (7.3)	5 (12.5)	8 (9.8)	
Never	35 (85.4)	33 (82.5)	68 (84.0)	NS
Divided stream**				
Sometimes	3 (7.3)	1 (2.5)	4 (4.9)	
Rarely	3 (7.3)	5 (12.5)	8 (9.9)	
Never	35 (85.4)	34 (85.0)	69 (85.2)	NS
Hematuria				
Sometimes	1 (2.4)	0 (0.0)	1 (1.2)	
Rarely	0 (0.0)	1 (2.5)	1 (1.2)	
Never	41 (97.6)	39 (97.5)	80 (97.6)	NS
Frequency				
Always	5 (11.9)	0 (0.0)	5 (6.1)	

Often	1 (2.4)	3 (7.5)	4 (4.9)	
Sometimes	15 (35.7)	18 (45.0)	33 (40.2)	
Rarely	9 (21.4)	5 (12.5)	14 (17.1)	
Never	12 (28.6)	14 (35.0)	26 (31.7)	NS
Urgency**				
Always	2 (4.9)	0 (0.0)	2 (2.5)	
Often	2 (4.9)	2 (5.0)	4 (4.9)	
Sometimes	5 (12.2)	10 (25.0)	15 (18.5)	
Rarely	13 (31.7)	10 (25.0)	23 (28.4)	
Never	19 (46.3)	18 (45.0)	37 (45.7)	NS

* Pearson chi-square ** missing one case NS = non-significant

4.5 Comorbid health problems:

Allergic rhinitis and frequent constipation were the commonest co-morbid health problems among enuretic children as reported among 23.2% and 20.7% of them, respectively. Head trauma was reported by 12.2% of the participants whereas frequent urinary tract infections were mentioned by 6.1% of them. There was no statistically significant difference between children in the intervention group and those in the control group regarding co-morbid health problems as clear in Table 4.

Table 4: Distribution of the Co-morbid health problems among children with enuresis

	Intervention group **n**=42 N (%)	Control group **n**=40 N (%)	Total 82 N (%)	p-value*
Frequent urinary tract infections	2 (4.8)	3 (7.5)	5 (6.1)	NS
Congenital anomalies at birth	3 (7.1)	0 (0.0)	3 (3.7)	NS
Sickle cell anemia	0 (0.0)	1 (2.5)	1 (1.2)	NS
Psychological problems/ diseases	2 (4.8)	0 (0.0)	2 (2.4)	NS
Head trauma	6 (14.3)	4 (10.0)	10 (12.2)	NS
Frequent constipation	6 (14.3)	11 (27.5)	17 (20.7)	NS
Allergic rhinitis	11 (26.2)	8 (20.0)	19 (23.2)	NS

* Fischer exact test NS = non-significant

4.6 Management:

The most frequent reported measure was used to manage enuresis before an intervention was voiding before going to bed (89%), followed by encouraging the child if he/she is dry (69.5%), waking the child from sleep for voiding (59.8%) and rebuke the enuretic child (32.9%). Parental punishment and wearing a diaper was reported among 25.6% and 24.4% of the participants, respectively. There was no statistically significant difference between children in the intervention group and those in the control group regarding management measures as shown in table 5.

Table 5: Management of enuresis among the participants before the intervention.

	Intervention group **n**=42 N (%)	Control group **n**=40 N (%)	Total 82 N (%)	p-value
Use of medications	1 (2.4)	0 (0.0)	1 (1.2)	NS**
Physician consultation	3 (7.1)	0 (0.0)	3 (3.7)	NS**
Decrease fluid intake and diuretics	28 (66.7)	26 (65.9)	54 (6.1)	NS*
Encourage the child if he/she is dry	27 (64.3)	30 (75.0)	57 (69.5)	NS*
Wear diaper	13 (31.0)	7 (17.5)	20 (24.4)	NS*
Voiding before going to bed	36 (85.7)	37 (92.5)	73 (89.0)	NS**
Waking child from sleep for voiding	26 (61.9)	23 (57.5)	49 (59.8)	NS*
Parental punishment	9 (21.4)	12 (30.0)	21 (25.6)	NS*
Rebuke the enuretic child	12 (28.6)	15 (37.5)	27 (32.9)	NS*
mockery the enuretic child	3 (7.1)	4 (10.0)	7 (8.5)	NS*

* Pearson chi-square ** Fischer exact test NS = non-significant

4.7 Comparison of Nocturnal Enuresis between the two groups

As demonstrated in table 6, the rates of nocturnal bed wetting (days/week) at baseline, after one month, after two months and after three months were less among the control group more than the intervention group but the result wasnot statistically significant.

Table 6: Comparison of nocturnal bed wetting between intervention group and control group

Nocturnal bed wetting (days/week)	Intervention group (n=42)	Control group (n=40)	p-value*
Baseline Median IQR Mean Rank	 5.0 3-5.25 45.74	 4.0 3-5.0 37.05	 NS
	Intervention group (n=40)	Control group (n=39)	
After one month Median IQR Mean Rank	 2 1-4.75 42.98	 1 0-4 36.95	 NS

	Intervention group (n=35)	Control group (n=37)	
After 2 months Median IQR Mean Rank	2 0-3 37.70	1 0-3.5 35.36	NS
	Intervention group (n=30)	Control group (n=34)	
After 3 months Median IQR Mean Rank	1 0-2 31.92	1 0-3 33.01	NS

* Mann-Whitney test NS = non-significant

4.8Comparison of Diurnal wetting between the two groups

It is clear from table 7 that there was no statistically significant difference between the intervention and control group regarding diurnal wetting (days/week) at baseline, after one month, after two months and after 3 months.

Table 7: Comparison of diurnal wetting between intervention group and control group

Diurnal enuresis (days/week)	Intervention group (n=42)	Control group (n=40)	p-value*
Baseline Median IQR Mean Rank	0.0 0.0-1.0 42.0	0.0 0.0-1.0 40.98	NS
	Intervention group (n=40)	Control group (n=39)	
After 1 month Median IQR Mean Rank	0 0.0-0.0 41.48	0 0.0-0.0 38.49	NS
	Intervention group (n=35)	Control group (n=37)	
After 2 months Median IQR Mean Rank	0 0.0-0.0 36.54	0 0.0-0.0 36.46	NS

	Intervention group (n=31)	Control group (n=34)	
After 3 months			
Median	0	0	
IQR	0.0-0.0	0.0-0.0	
Mean Rank	33.06	32.94	NS

NS = non-significant

4.9Follow up of nocturnal enuresis :

4.9.1In the Intervention group

As shown in table 8, there was a statistically significant reduction in the number of nocturnal bed wetting (days/week) between baseline and follow-up periods at one, two and three months, p <0.01. Similarly, there was a statistically significant reduction in the number of diurnal wetting (days/week) between baseline and follow-up periods at one p<0.01, two p<0.01 and three months p<0.01.

Table 8: Nocturnal enuresis (days/week) in the intervention group at baseline and follow-up periods.

Nocturnal bed wetting (days/week)	**Baseline n=42**	**After 1 Month n=40**	**After 2 months n=35**	**After 3 months n=30**
Median	5.0	2.0	2.0	1.0
IQR	3.0-5.25	1.0-4.75	0.0-3.0	0.0-2.0
z-value		-4.722	-4.519	-4.697
P-value*		<0.001	<0.001	<0.001

* Wilcoxon matched pairs signed rank test

4.9.2In a control group:

Table 9 showed that there was a statistically significant reduction in the number of nocturnal bed wetting (days/week) between baseline and follow-up periods at one, two and three months, p <0.01. Similarly, there was a statistically significant reduction in the number of diurnal wetting (days/week) between baseline and follow-up periods at one p<0.01, two p<0.01 and three months p<0.01.

Table 9: Nocturnal enuresis (days/week) in the control group at baseline and follow-up periods.

Nocturnal bed wetting (days/week)	**Baseline n=40**	**After 1 Month n=39**	**After 2 months n=37**	**After 3 months n=34**
Median	4.0	1.0	1.0	1.0
IQR	3.0-5.0	0.0-4.0	0.0-3.5	0.0-3.0
z-value		-4.638	-4.501	-4.360
P-value*		<0.001	<0.001	<0.001

* Wilcoxon matched-pairs signed-rank test

4.10 Improvement of nocturnal Enuresis:

Figure 5 is shown that the improvement in nocturnal enuresis was reported among 16.5% of the participants (13 out of 79) in the first month, whereas it increased to 35.6% (26 out of 73) in the second month, then slightly declined at third month (35.4%; 23 out of 65).

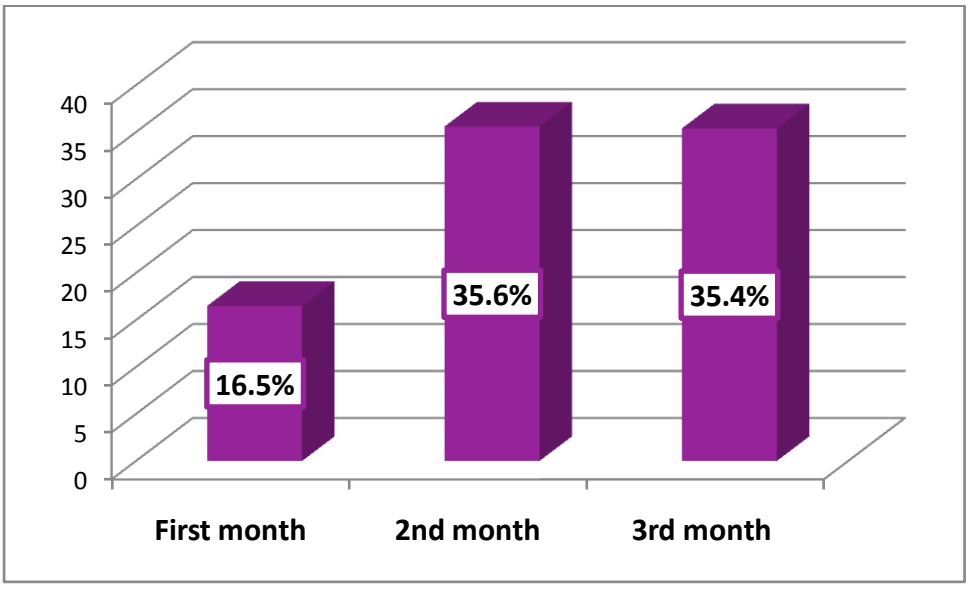

Figure 5: Improvement in nocturnal enuresis according to the follow-up time

4.11 Factors Associated with improvement at third month:

4.11.1. Socio-demographic factors

The highest rate of improvement in nocturnal enuresis at the third month of follow up was observed among children whose family income was ≤5000 SR/month (58.8%) while the lowest rate of improvement was reported among those whose family income ranged between 5001-8000 SR/month (8.3%) $p<0.05$. All other studied socio-demographic factors were not significantly associated with the improvement of nocturnal enuresis during the third month of follow-up as clear in table 10.

Table 10: Association between socio-demographic characteristics ofenuretic children and improvement in nocturnal enuresis at third month of follow-up

Socio-demographic characteristics	Improvement at third month of follow-up		p-value
	No n=42 N(%)	**Yes n=23 N(%)**	
Group			
Intervention (n=30)	20 (66.7)	10 (33.3)	
Control (n=35)	22 (62.9)	13 (37.1)	NS
Gender			
Male (n=40)	27 (67.5)	13 (32.5)	
Female (n=25)	15 (60.0)	10 (40.0)	NS
Age (years)			
3-5 (n=16)	12 (75.0)	4 (25.0)	
>5-5.5 (n=24)	13 (54.2)	11 (45.8)	
>5.5-6 (n=25)	17 (68.0)	8 (32.0)	NS
Nationality (n=64)			
Saudi (n=61)	39 (63.9)	22 (36.1)	
Non-Saudi (n=3)	3 (100)	0 (0.0)	NS*
Age at toilet training (years)			
≤2 (n=19)	10 (52.6)	9 (47.4)	
2.5 (n=20)	14 (70.0)	6 (30.0)	
3 (n=16)	13 (81.2)	3 (18.8)	
≥3.5 (n=10)	5 (50.0)	5 (50.0)	NS
Type of housing			
Flat (n=56)	34 (60.7)	22 (39.3)	
Others (n=9)	8 (88.9)	1 (11.1)	NS*
Number of rooms (n=64)			
≤4 (n=36)	22 (61.1)	14 (38.9)	
>4 (n=28)	19 (67.9)	9 (32.1)	NS
Number of bed rooms (n=64)			
≤2 (n=48)	29 (60.4)	19 (39.6)	
>2 (n=16)	12 (75.0)	4 (25.0)	NS*
Number of bathrooms			
≤2 (n=31)	19 (61.3)	12 (38.7)	
3 (n=23)	17 (73.9)	6 (26.1)	
≥4 (n=11)	6 (54.5)	5 (45.5)	NS
Paternal education (n=65)			
≤Secondary //Diploma (n=31)	20 (64.5)	11 (35.5)	
University/above (n=34)	22 (64.7)	12 (35.3)	NS
Maternal education			
≤Secondary/Diploma (n=21)	15 (71.4)	6 (28.6)	
University/above (n=44)	27 (61.4)	17 (38.6)	NS
Parental consanguinity			
Yes (n=14)	9 (64.3)	5 (35.7)	NS
No (n=51)	33 (64.7)	18 (35.3)	

With whom child live			
Both parents (n=62)	40 (64.5)	22 (35.5)	
Mother (n=3)	2 (66.7)	1 (33.3)	NS
Income (SR/month) (n=62)			
≤5000 (n=17)	7 (41.2)	10 (58.8)	
5001-8000 (n=12)	11 (91.7)	1 (8.3)	
8001-10000 (n=20)	14 (70.0)	6 (30.0)	
>10000 (n=13)	8 (61.5)	5 (38.5)	0.042

***** Fischer exact NS = non-significant

4.11.2.Frequency of nocturnal enuresis at baseline (days/week)

All enuretic children with high frequency of nocturnal enuresis at baseline (7 days out of 7 days) compared to 37.5% of those with a frequency of 3 days out of 7 days were not improved at the third month of follow-up, p<0.04.

Table 11: Association between frequency of nocturnal enuresis (days/week) at baseline and improvement at the third month of follow-up

frequency of nocturnal enuresis (days/week)	Improvement at third month of follow-up		p-value*
	NO n=42 N(%)	**YES n=23 N(%)**	
0 (n=1)	1 (100)	0 (0.0)	
1 (n=1)	1 (100)	0 (0.0)	
2 (n=10)	4 (40.0)	6 (60.0)	
3 (n=16)	6 (37.5)	10 (62.5)	
4 (n=13)	11 (84.6)	2 (15.4)	
5 (n=12)	9 (75.0)	3 (25.0)	
6 (n=6)	4 (66.7)	2 (33.3)	
7 (n=6)	6 (100)	0 (0.0)	0.036

*** Chi-square test**

4.11.3. Co-intervention

the mother of children sometimes used other interventions to help their child to stay dry. They mostly lifting their child from sleep to the toilet. There was no statistically significant association between co-intervention and improvement in nocturnal enuresis at the third month of follow up as shown in table 12.

Table 12: Association between co-intervention and improvement of nocturnal enuresis at the third month of follow-up

Co-intervention during the study	Improvement at third month of follow-up		p-value*
	NO n=42 N(%)	**YES n=23 N(%)**	
Yes (n=38)	28 (73.7)	10 (26.3)	

No (n=27)	14 (51.9)	13 (48.1)	0.070

*** Chi-square test**

V. Discussion

As parents of the enuretic children should have a vital role in the management through encouraging and supporting their child,[11]this study was conducted to evaluate the impact of motivational therapy moreover behavioral therapy in improvement of children with enuresis as well as to identify factors associated with improvement of children with enuresis treated by behavioral and/or motivational therapy in MakkahAl-Mukarramah.

Response rate

In the present study, the response rates after three months of follow-up were acceptable in both intervention (73.8%) and control groups (85%). These high rates could be attributed to the effort done as the researcher followed the children weekly over a period of 12 weeks to encourage parents to respond.

Management

In the present study, the commonest measure used to manage enuresis among children of both groups was alleviation of stressor (punishment, and mockery), decrease the fluid intake before sleep, avoid diuretic food and drinks, avoid wearing child diapers,voiding before going to bed and encouraging the child if he/she is dry. Furthermore, star chart and rewards for the intervention group

Caldwell et al. showed that simple behavioral intervention is better than no treatment for the enuretic patients.[7]Glazener CM and Evans JH documented that reward system or waking a child to void in the toilet may be effective for the management of enuresis.[13]Canadian Paediatric Societyconcluded that behavioral therapy such as wakening child to bathroom and star chart may consider a successful option for some children.[6]

Improvement of nocturnal enuresis

In the current trial, the improvementin nocturnal enuresis was reported among 16.5% of the participants in the first month, whereas it increased to 35.6% in the second month, and then slightly declined at the third month 35.4%. In a previous similar study carried out by Al-Matrafi (2015),[15]different figures were obtained as the degree of improvement was 99.3% in the first month, 36% in the first 2 months, and 9% in the first 3 months. The difference in the rates of improvement between the two studies could be attributed to the difference in demographics of patients, particularly the age, degree of enuresis and methods of management applied. In the present study, the degree of improvement was highest at the end of second month, then slightly declined whereas in Al-Matrafi`s study,[15]the degree of improvement was highest in the first month and decreased subsequently in the second and third months. In the present study, the improvement was considered in the case of zero wetting per week for 2 consecutive weeks. In Canada, the rate of improvement was 70% among children aged over 7 years with a frequency of less than 3 times per week per 6 months.[20]In Lebanon, Merhi BA et al (2014) reported a rate of improvement as 50% among children aged below 7 years with wetting frequency of less than or equal two times per week for 6 months.[21]In Turkey, the rate of improvement among children aged between 7 and 11 years was 40%.[22]So, the definition of improvement is another important factor explaining the difference in the rate of improvement between various studies.

The current study was carried out in February, March, and April and the first two months consider relatively cold in Saudi Arabia and this could be a reason for increased improvement with months progressing. This finding agreed with what has been reported by Tuncay et al.the enuresis rate improved during summer months versus winter months.[10]

In the present study, there was no difference between the intervention group (treated with behavioral therapy and star charts) and the control group of enuretic children (treated with only behavioral therapy)regarding the rate of improvement at the end of the third month of follow-up. A relatively small sample size adopted in the present study could be a factor behind this finding. Therefore, a larger multi-centric study with more sample size is recommended. In South Holland, four groups of enuretic children were treated differently by wakening and lifting the child to the the bathroom and ask for a password, wakening and lifting the child to the bathroom without asking for a password, using of reward and star chartwith written and printed instructions. They revealed that wakening and lifting child to the bathroom is more effective in the dryness of enuretic children than no treatment after six months.Furthermore, the use of the reward system (star chart) was the most effective treatment of nocturnal enuresis in the first 15 weeks while wakening and lifting the child to the bathroom without a password was most effective after 15 weeks. Moreover, the reward system such as star chart associated with higher cure rate, less wet night and low relapse rate.[16]

Factors associated with improvement

Regarding factors associated with improvement in nocturnal enuresis, in the present study, children whose family income was lowest expressed the highest rate of improvement. We could not explain this finding as it was not reported previously in any study.

The child's age was not a predictor for improvement of enuresis after behavioral/motivational therapy in the present study. However, Al-Matrafi HA[15] observed that the mean age of children with improved enuresis was higher than that of the children with non-improved enuresis inthe first 3 months of follow-up.She explained this to the peer and/or community pressure. Alwan et al. [25] showed more improvement among children aged below 7 of years age group. whereas Gümüş et al. [22]reported that the child's age of less than 9 years was associated with a more positive outcome.

The gender of the child was not a significant predictor of improvement of enuresis in this study. This finding agreed with what has been reported by Longstaffe et al.[20]However, in a study carried out by Al-Matrafi HA,[15]improvement was reported among male children. She attributed this to the anatomical differences as females are more susceptible to recurrent infections more than males.On the other hand, Gümüş et al.[22]observed more improvement among females, where the age of enuretic children was below 9 years and improvement was defined as bedwetting frequency of less than twice times per week for 8 weeks.

In the present study, the age of toilet training was not related to improvement in nocturnal enuresis. The reported age of toilet training in our community was around 2 years.[15]This is probably the reason for not having a significant association of age at toilet training with improvement. Kiddoo DA showed that early toilet training was associated with a better improvement of enuresis.[23]According to DSM-V, the age of the child should be at least 5 years for the diagnosis of enuresis.[8]In the present study, 23.2% of included children were less than 5 years of age. However, it has been documented that most children start toilet training between 2 and 3 years and simple behavioral intervention may be effective.[24]

In this study, a high frequency of nocturnal enuresis at baseline was related to non-improvement of enuresis at the third month of follow-up. The same has been observed in a previous Saudi study carried out by Al-Matrafi HA.[15]

Up to our knowledge, this is the first study of its kind to compare the behavioral therapy only with behavioral therapy in addition to motivational therapy (star chart) in the management of enuresis in Makkah Region and even in the whole kingdom of Saudi Arabia. However, it has one important limitation that should be mentioned.The relatively small sample size did not allow us to find statistically significant findings on many occasions.

Conclusion

This study revealed that there is an improvement of enuresis among children after motivational and/or behavioral therapy. Motivational therapy did not add to the improvement produced by behavioral therapy in enuresis. The rate of improvement of zero wetting per week was low in the first month and then increased in the first 2nd months and declined slightly in the 3rd month. The improvement was associated with the economic status of the family of the affected child and the frequency of bed-wetting before starting the intervention. It did not affect by the method of managem.

Recommendation

1. Organization health education program at primary health care centers for parents of enuretic children regarding the importance of behavioral and motivational therapy in the management of enuresis is needed.
2. Training of primary healthcare physicians in behavioral and motivational therapy for the management of nocturnal enuresis.
3. Encourage healthcare workers to emphasize the importance of behavioral/ motivational therapy to parents of enuretic children.
4. Encourage parents to seek medical advice for the problem of enuresis among their children and not to be shame of that.
5. Further larger multi-centric study with more sample size is recommended.

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KINGDOM OF SAUDI ARABIA
MINISTRY OF INTERIOR
General Administration for Medical Service
Security Forces Hospital Program
Makkah

Institutional Review Board Opinion Letter

Protocol Title	The effect and the determinants of behavioral and motivational therapy among children with enuresis in kindergarten, Makkah Al-Mukarramah,Saudi Arabia,2018. A randomized controlled trial.
Version	0.1
Principal investigator	Fatima Bobakr Al-Nahdi
IRB number	0160-220118
Sponsor	-

Dear Dr. Fatima,

This is to inform you that the above mentioned proposal has been the subject of full board review by SFHM IRB registered at the National BioMedical Ethics Committee, King Abdulaziz City for Science and Technology on 7/7/1436 (Registration no. HAP-02-K-052).

The decision for **full board review** was based on:

1. E-IRB submitted documents (protocol version 1.0)

The opinion of the IRB committee is to **approve** the above mentioned proposal on 30/01/2018.

Full board conditions:

- Patient nominative identifiers should be removed from all questionnaires.
- Patient nominative identifiers should be removed on the extraction sheet, and serial number will be used.
- Maintaining patient confidentiality during publication

Dr. Mohammed Al Shareef — **30/01/2018**

(Name of IRB Chair) *(Signature)* *DD/MM/YYYY (Date)*

IRB

تلفون: ٠١٢ ٥٢٧٨٨٨٨ - فاكس: ٠١٢ ٥٢٧٩٠٠٠ - ص.ب: ١٤٧٩٩ - مكة: ٢١٩٥٥ - المملكة العربية السعودية
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